UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

JOSHUA DAVID FRISKE, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF KATHRYN FRISKE; JEREMY FRISKE, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF KATHRYN FRISKE; BILLY RAY STAPP; AND GLORIA STAPP, Plaintiffs, vs. ALZA CORPORATION AND SANDOZ INC., Defendants.	CIVIL ACTION NO. 3:11–CV–130–F

DEFENDANTS' REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR PARTIAL DISMISSAL

As Defendants explain in their motion for partial dismissal, the FDA-approved warnings for the fentanyl patch at issue (the "Patch") are presumed adequate under Texas law and the only exception Plaintiffs allege (fraud-on-the-FDA) is preempted by federal law. Plaintiffs do not deny these points. Instead, they argue they do not have to plead an exception to the presumption against liability and are entitled to establish an exception through discovery. No amount of discovery will save their warnings defect claims, which are barred as a matter of law.

Further, Texas law and comment k to section 402A of the RESTATEMENT (SECOND) OF TORTS bar design defect claims concerning prescription drugs such as the Patch. Plaintiffs misinterpret the law and argue that this rule is inapplicable because the Patch is merely a "container" for the active ingredient fentanyl. The complaint and relevant authorities establish that the Patch is a prescription drug immune from design defect liability.

Defendants seek dismissal of Plaintiffs' warning and design defect claims in both strict liability and negligence. Plaintiffs erroneously state that Defendants do not attack their negligence claims. Plaintiffs do not explain why their warning and design defect claims should survive in negligence if they fail in strict liability.

Defendants also move to dismiss Plaintiffs' implied warranty of fitness claim. Plaintiffs do not oppose that part of the motion, and thus concede that claim should be dismissed.

I. PLAINTIFFS' WARNINGS DEFECT CLAIMS FAIL AS A MATTER OF LAW

A. A Motion to Dismiss is the Proper Procedure to Dispose of Plaintiffs' Claims

Plaintiffs do not dispute that Section 82.007 of the Texas Civil Practice & Remedies Code presumptively bars actions based on FDA-approved warnings, and the only exception they allege (fraud-on-the-FDA) is preempted. Motion, pp. 3-16. Instead, they argue that they are not required to plead facts to refute the presumption of non-liability, and that they are entitled to conduct discovery to establish a statutory exception. Response, pp. 4-17.

Plaintiffs cite *In re Electronic Data Systems Corp. "ERISA" Litigation ("EDS")*, 305 F.

Supp. 2d 658 (E.D. Tex. 2004) and *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002) in an effort to support their argument that they have no duty to plead facts rebutting a presumption. Those cases are inapposite. The *EDS* court held that the plaintiffs were not required to plead facts rebutting the presumption that an investment in an employee stock option plan ("ESOP") is prudent because "discovery could establish that the Plan is not an ESOP and thus the ESOP presumption is inapplicable. Indeed, the Court is not certain that the Plan is an ESOP." *EDS,* 305 F. Supp. 2d at 670. The court followed *Swierkiewicz,* where "the Supreme Court noted that revelations in discovery" could affect the proof required at trial. *Id.* The *Swierkiewicz* Court held that the plaintiff was not required to plead facts supporting a prima facie discrimination case under *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973) because, ultimately, the plaintiff may not even be required to *prove* such facts:

> [I]t is not appropriate to require a plaintiff to plead facts establishing a prima facie case because the *McDonnell Douglas* framework does not apply in every case. For instance, if a plaintiff is able to produce direct evidence of discrimination, he may prevail without proving all the elements of a prima facie case. . . . It thus seems incongruous to require a plaintiff, in order to survive a motion to dismiss, to plead more facts than he may ultimately need to prove to succeed on the merits if direct evidence of discrimination is discovered. . . . Given that the prima facie case operates as a flexible evidentiary standard, it should not be transposed into a rigid pleading standard for discrimination cases.

Swierkiewicz, 534 U.S. at 511-12.

Swierkiewicz and *EDS* relied on the fact that discovery could uncover evidence allowing the claims at issue there to survive. Here, no amount of discovery will make Plaintiffs' fraud-on-the-FDA allegations sufficient to overcome the presumption against liability for FDA-approved warnings. *See* Motion, pp. 2-13. By alleging that the FDA approved the warnings for the Patch, Plaintiffs triggered the presumption against liability for any alleged defects in those warnings. *See In re Katrina Canal Breaches Litig.,* 495 F.3d 191, 205 (5th Cir. 2007) (In deciding a motion to dismiss for failure to state a claim, "[t]he court accepts all well-pleaded facts as true. . . .").

Courts have not followed *Swierkiewicz* and *EDS* since the Supreme Court subsequently

decided *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, — U.S. —, 129 S.Ct. 1937 (2009). In *Sablan v. A.B. Won Pat Int'l Airport Auth., Guam*, No. 10-00013, 2010 WL 5148202 (D. Guam Dec. 9, 2010) (Tydingco-Gatewood, J.), the court explained the new "plausibility standard" for pleadings, "under which a complaint cannot survive a Rule 12(b)(6) motion to dismiss unless it contains 'well-pleaded facts' that . . . positively 'allow[ ] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id.* at *3, quoting *Iqbal*, 129 S.Ct. at 1949-50. Moreover, "at least one federal appellate court has concluded that *Twombly* and *Iqbal* overruled *Swierkiewicz sub silentio.*" *Id.* at *3, citing *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009).

In *Puente v. Ridge*, 324 F. App'x. 423, 428, 2009 WL 1311504 (5th Cir. 2009), the Fifth Circuit affirmed an order dismissing a discrimination claim, like that in *Swierkiewicz*, under Rule 12(b)(6). *Id.* at *3 ("[T]his court may consider the *McDonnell Douglas* framework, and no plaintiff is exempt from her obligation to 'allege facts sufficient to state all the elements of her claim.'"). Similarly, the Northern District of Texas recently held that discrimination claims were subject to dismissal where the allegations were not as specific as those in *Swierkiewicz*. *Whitworth v. Mouser Electronics, Inc.*, No. 3:10-CV-1134-L, 2010 WL 4628068, *3 (N.D. Tex. Nov. 8, 2010) (Lindsay, J.) ("[T]he level of specificity in Plaintiff's Complaint is far less specific than that in *Swierkiewicz*. Accordingly, the allegations in Plaintiff's Complaint fail the necessary test to comply with Rule 8 and to defeat a Rule 12(b)(6) motion.")

In *Edgar v. Avaya, Inc.*, 503 F.3d 340 (3d Cir. 2007), the plaintiff argued it was improper to consider the presumption of prudence in investing in ESOPs – the same presumption at issue in *EDS* – in ruling on a motion to dismiss. *Id.* at 349. The court rejected that argument, finding that "a duty of prudence claim that is on its face inadequate as a matter of law obviates the need for discovery." *Id.* As Plaintiffs' warnings claims are presumptively barred – and the fraud-on-the-FDA exception they allege is preempted – there is no need for discovery as to those claims.

By analogy, "[a] statute of limitations may support dismissal under Rule 12(b)(6) when it is evident from the plaintiff's pleadings that the action is barred and the pleadings fail to raise some basis for tolling the like." *Jones v. Alcoa, Inc.*, 339 F.3d 359, 366 (5th Cir. 2003). This is true even though statutes of limitations are affirmative defenses which defendants have the burden to establish. *See Capital One Bank (USA), N.A. v. Conti*, No. 04-10-00295, 2011 WL 313841, *1 (Tex. App.—San Antonio Feb. 2, 2011).

While Plaintiffs allege the fraud-on-the-FDA exception in Section 82.007(b)(1), they do not allege any other exceptions to the presumption of non-liability for FDA-approved warnings under Section 82.007(b)(2)-(5) (*e.g.*, that Defendants: sold the product after the FDA ordered it withdrawn from the market (or that the FDA ever withdrew its approval of the product); recommended any off-label use of the product; or committed bribery). In the absence of any such allegations, the Court should assume no such facts exist. *Puente v. Ridge*, 324 F. App'x. 423, 428, 2009 WL 1311504, *4 (5th Cir. 2009) ("[W]hen a complaint omits facts that, if they existed, would clearly dominate the case, it seems fair to assume that those facts do not exist.")

As Plaintiffs have alleged that the FDA approved the warnings at issue, Section 82.007's presumption against liability applies. The fraud-on-the-FDA exception is preempted for the reasons stated in Section II.A. of Defendants' motion – which Plaintiffs do not dispute and therefore concede (*see* § IV, *infra*) – and Plaintiffs have not alleged any other exception.

B. The Presumption Against Liability for FDA-Approved Warnings is Not an "Evidentiary" Presumption

Plaintiffs argue that a motion to dismiss is improper where "evidentiary" presumptions are at issue. They characterize the presumption against non-liability in Section 82.007 as an evidentiary presumption which would "shift the burden of producing evidence to the party against whom it operates." Response, p. 6, citing *Gen. Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex. 1993). That argument is inconsistent with Section 82.007(b), which states that the presumption can only be rebutted by "*establishing*" a particular fact, like fraud on the FDA.

Under an evidentiary presumption, "finding a basic fact gives rise to the existence of a presumed fact until the presumption is rebutted." *Leskinen v. Burford*, 892 S.W.2d 135, 136 (quoting TEX. PROP. CODE ANN. § 92.108 (Vernon 1984) (Revisor's Note)). In other words, evidentiary presumptions tip the scale in favor of the existence of a particular fact at trial. To rebut such a presumption, evidence must be introduced undermining the presumed fact.

Under Section 82.007's no-liability rule, FDA approval does not lead to a presumption of any "evidentiary" fact, the truth of which could be rebutted with evidence. Rather, FDA approval leads to the presumption that the defendants "*are not liable*" on a failure-to-warn theory. Moreover, the exceptions listed in subsection (b) all go to whether the presumption itself is justified, *i.e.*, whether the fact of FDA approval in fact should lead to the conclusion that the defendant is not responsible – and thus not liable – for the warnings at issue.

C. Plaintiffs' Misrepresentation Claims Are Not Adequately Pleaded

The Court should dismiss Plaintiffs' misrepresentation claims (whether fraudulent or negligent) because they have not alleged facts sufficient to support such a claim under Rule 9(b). Motion, pp. 13-16. In their response to Defendants' motion, Plaintiffs suggest that "after Defendants knew that proper use of the Patch could cause injury or death, Defendants continued to represent that the patch was safe…." Response, p. 15. That allegation is insufficient. *See, e.g., Williams v. WMX Techs., Inc.*, 112 F.3d 175, 177 (5th Cir. 1997) (requiring plaintiffs to "specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent.").

II. PLAINTIFFS' DESIGN DEFECT CLAIMS ARE BARRED UNDER TEXAS LAW

A. Texas law and comment k bar design defect claims as to prescription drugs

Plaintiffs argue that their design defect claims should survive because: Texas law and comment k do not bar design defect claims for all prescription drugs; the Patch is a "container"

for fentanyl and is not a "drug"; and Texas law only bars design defect claims sounding in strict liability, not negligence. Response, pp. 21-22. None of those arguments is tenable.

Plaintiffs suggest that *Hackett v. G.D. Searle & Co.,* 246 F. Supp. 2d 591 (W.D. Tex. 2002) narrowly held that Texas law and comment k bar design defect claims concerning the prescription pain medication Celebrex only. Response, p. 18. To the contrary, the rule in *Hackett* bars design defect claims with respect to all prescription drugs in Texas. The *Hackett* defendants argued that Celbrex was "unavoidably unsafe" and therefore immune from design defect liability under comment k. *Id.* at 595. The court recognized that "Texas courts apply comment k to product liability claims, and have applied it to prescription drug claims." *Id.,* citing *Reyes v. Wyeth Labs.,* 498 F.2d 1264, 1273-75 (5th Cir. 1974) (holding that the polio vaccine, a prescription drug, was an unavoidably unsafe product). The court noted:

> Celebrex is a prescription drug. . . . Defendants do not present evidence that Celebrex in particular is an unavoidably unsafe drug; rather, they urge this Court to rule that all FDA-approved prescription drugs are unavoidably unsafe as a matter of law. Many courts have held FDA-approved prescription drugs unavoidably unsafe as a matter of law.

Id., citing *Grundberg v. Upjohn Co.,* 813 P.2d 89, 98-99 (Utah 1991); *Brown v. Super. Ct.,* 751 P.2d 470, 482-83 (Cal. 1988); *Lindsay v. Ortho Pharm. Corp.,* 637 F.2d 87, 90-91 (2d Cir. 1980). The court agreed with the defendants and held that the plaintiff could not state a claim for design defect because the product at issue was a prescription drug. *Id.* at 595 ("To allow plaintiffs to sue for defective design of prescription drugs would provide a disincentive to companies to develop new drugs and would allow juries to second-guess the FDA's approval of the drugs for marketing."). The court did not limit its holding to a particular drug.

As the California Supreme Court noted in *Brown v. Superior Court,* "the comment was intended to and should apply to all prescription drugs." 44 Cal.3d at 482 n. 11. Similarly, in *Grundberg v. Upjohn Co.,* the Utah Supreme Court held that "all prescription drugs should be classified as unavoidably dangerous in design because of their unique nature and value, the

elaborate regulatory system overseen by the FDA, the difficulties of relying on individual lawsuits as a forum in which to review a prescription drug's design, and the significant public policy considerations noted in *Brown*." 813 P.2d at 95.

B. The Patch is a Prescription Drug, Not Merely a Fentanyl "Container"

Plaintiffs attempt to circumvent the law barring prescription drug design defect claims by arguing that the Patch is merely a "container" for the drug and not a drug itself. That argument contradicts the allegations in the Complaint, United States Supreme Court precedent, and the Code of Federal Regulations. Plaintiffs allege the decedent was prescribed *the Patch*, not merely the fentanyl inside the patch. Complaint, p. 5, ¶¶ 3, 7. There is no exception to the rule against liability for drug design defects based on how the active ingredient is delivered. Every drug has a delivery system – whether intravenous, intramuscular, oral, transmucosal, or transdermal. The Patch is a "multi-layer system" that includes a rate-controlling membrane, allowing the release of fentanyl at a "steady rate" when applied to the patient's skin. (Complaint, p. 6, ¶ 9; 7, ¶ 13.) The Patch plays a role in the rate of delivery of fentanyl and is not merely a "container" (like a box in which it is sold or a tube through which fentanyl flows).

In *U.S. v. Generix Drug Corp*., 460 U.S. 453 (1983), the government sought to enjoin a generic prescription drug manufacturer from selling drugs not approved through the New Drug Application process under federal law. The Supreme Court rejected the argument that the generic drugs were not "new drugs" that needed FDA approval because their active ingredients were previously approved in brand-name drugs. The Court held that the definition of a "drug" cannot be limited to an active ingredient: "[W]e are required to determine whether the term 'drug' as used in the relevant sections of the Federal Food, Drug, and Cosmetic Act…refers only to the active ingredient in a drug product or to the entire product. We hold that Congress intended the word to have the broader meaning." *Id.* at 454. The Court noted: "The active ingredients in most prescription drugs constitute less than 10% of the product; inactive

'excipients' (such as coatings, binders, and capsules) constitute the rest." *Id.* The Court explained how "differences in excipients may affect the safety and effectiveness of drug products. Excipients may affect the rate at which the active ingredient is delivered to a diseased organ. If delivery is too fast, the patient may be harmed just as if he received an overdose; if delivery is too slow, the treatment of the disease may be ineffective." *Id.* at 455. The Court concluded: "The term 'drug' is plainly intended throughout the Act to include entire drug products, complete with active and inactive ingredients." *Id.* at 459.

Here, the Patch, not just the active ingredient fentanyl, is a "drug" under federal law. The inactive ingredients of the patch are "excipients," just as coatings, binders, and capsules are excipients for orally-administered drugs. The Patch, consisting of fentanyl gel inside a transdermal system, is a drug product in final dosage form that is available only by prescription. Just as a capsule or tablet is in final dosage form that is intended to be swallowed by a patient, the Patch is in final dosage form because it is ready to be applied to patients' skin. The system as a whole, including active and inactive ingredients, is a prescription drug. *See* 21 C.F.R. §§ 208.3(e), 210.3(b)(4), 314.3(b), 320.1(b) ("Drug product means a finished dosage form, *e.g.*, tablet, capsule, or solution, that contains an active drug ingredient, generally . . . in association with inactive ingredients"); 21 U.S.C. § 379g(3) ("The term 'prescription drug product' means a specific strength or potency of a drug in final dosage form"); 21 C.F.R. §§ 203.3(y), 205.3(e) ("Prescription drug" includes "finished dosage forms"); 21 U.S.C. § 379g(4) (a "final dosage form" is a form "which is approved for administration to a patient without substantial further manufacturing (such as capsules, tablets, or lyophilized products before reconstitution)").

III. PLAINTIFFS' WARNING AND DESIGN DEFECT CLAIMS CANNOT SURVIVE IN STRICT LIABILITY OR NEGLIGENCE

In their moving papers, Defendants requested dismissal of Plaintiffs' warnings and design defect claims in strict liability as well as negligence. Motion, at Title Page & p. 19; *see also*

Proposed Order. Defendants did so because the same concerns would arise whether Plaintiffs stated those claims in terms of negligence or strict liability. In holding that Texas law bars prescription drug design defect claims, the *Hackett* court did not make a distinction between negligence and strict liability. The court recognized that allowing "plaintiffs to sue for defective design of prescription drugs would provide a disincentive to companies to develop new drugs and would allow juries to second-guess the FDA's approval." *Hackett*, 246 F. Supp. 2d at 595. Those problems would arise equally from suits brought in negligence and strict liability. *See also Jones v. NordicTrack, Inc.*, 550 S.E.2d 101, 103 n. 5 (Ga. 1999) ("there is no significant distinction between negligence and strict liability for the purposes of the risk-utility analysis").

The same principle applies to warnings defects. The Texas Legislature did not limit the presumption against liability for such defects to strict liability claims. Plaintiffs offer no reason why the Court should apply different analyses to their warning and design defects claims brought in strict liability on one hand and negligence on the other. Plaintiffs' only argument is that Defendants do not move to dismiss the negligence claims – which is inaccurate.

IV. PLAINTIFFS DO NOT CHALLENGE DEFENDANTS' MOTION TO DISMISS THE IMPLIED WARRANTY OF FITNESS CLAIM

Plaintiffs effectively concede each point in the moving papers which they fail to address in their response. *See, e.g., Kimbrough v. Alamo Colleges***,** Civ. No. SA-09-CV-0728, 2010 WL 841368 (W.D. Tex. Mar. 8, 2010) (Nowak, M.J.) (holding the plaintiff "impliedly conceded [a] point by failing to address [an] argument in his response" to a 12(b)(6) motion to dismiss); *Verges v. Daugherty Sys., Inc.*, No. CA 3-97-CV-2947-R, 1998 WL 574384, at *4 (N.D. Tex. Aug. 27, 1998) (Buchmeyer, J.) (mem. op.) (dismissing an action under 12(b)(6) due to the plaintiffs' failure to address the defendant's arguments); *VDV Media Corp. v. Relm Wireless, Inc.*, No. 2:05-CV-1877-H, 2006 WL 462436, *2 n. 2 (N.D. Tex. Feb. 27, 2006) (Sanders, J.); *Magee v. Life Ins. Co. of N. Am.*, 261 F. Supp. 2d 738, 748 (S.D. Tex. 2003) (where the plaintiff

"does not address preemption in her . . . response[,]. . . . . [s]he thus concedes . . . her state law claims are preempted.") (citing *Lookingbill v. Cockrell*, 293 F.3d 256, 264 (5th Cir. 2002)). As Plaintiffs fail to oppose Defendants' motion to dismiss the implied warranty claim – among other points – the Court should dismiss that claim for the reasons stated in the motion.

V. THE COURT SHOULD DENY PLAINTIFFS' INFORMAL MOTION FOR LEAVE TO AMEND

Plaintiffs informally request leave to amend their Complaint "[i]n the event that this Court finds that Plaintiffs have failed to adequately state any claim. . . ." Response, p. 23. Plaintiffs have not complied with Local Civil Rule LR 15.1, which requires any motion for leave to amend to be accompanied by a proposed amended complaint. Moreover, Plaintiffs have not identified any new allegations they would make in an attempt to cure their pleading deficiencies. Although Rule 15(a)(2) states that "the court should freely give leave [to amend] when justice so requires," FED. R. CIV. P. 15(a)(2), justice does not require allowing Plaintiffs to re-plead in this case. *See, e.g., Klein v. Gen. Nutrition Co., Inc.*, 186 F.3d 338, 346 (3d Cir. 1999) (holding that the court did not abuse its discretion in denying appellants leave to amend because, among other things, "instead of seeking leave to file another amendment, the plaintiffs chose to respond to defendants' second motion to dismiss," and the "appellants fail to identify any new facts that they would allege in a third complaint."); *Truk Int'l Fund LP v. Wehlmann*, 737 F. Supp. 2d 611, 625-26 (N.D. Tex. 2009). Re-pleading would be futile because Plaintiffs' claims fail as a matter of law. For these reasons, Plaintiffs' request for leave to amend should be denied.

VI. CONCLUSION

For the reasons stated in Defendants' motion and this reply brief, the Court should grant Defendants' motion for partial dismissal in its entirety. By dismissing Plaintiffs' warnings and design defect claims, the Court will allow the parties to focus on the real issue in this case – whether or not the Patch "malfunctioned and did not perform as intended and designed" as a result of a manufacturing defect "involving seal integrity." Complaint, p. 11, ¶ 11; p. 13, ¶ 19.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that this document was filed electronically on the 1st day of April, 2011, and, in compliance with Local Civil Rule LR 5.1(d), a copy of this document has been served on counsel for Plaintiffs.

David C. Schulte